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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/538,245

06/07/2005

David Feifel

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EXAMINER

DUTT, ADITI

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/538,245	<b>Applicant(s)</b> FEIFEL, DAVID	
	<b>Examiner</b> Aditi Dutt	<b>Art Unit</b> 1649	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 15-18,22 and 24-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-18,22 and 24-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Claims***

1. The amendment filed on 13 April 2009 has been entered into the record and has been fully considered. Claims 15-18, 24 and 26 are amended.
2. Claims 15-18, 22, and 24-26, drawn to a method for increasing sensorimotor gating or inhibiting serotonin-2A and/or alpha-1 receptor mediated neural function by administration of neurotensin agonist to a subject, are being considered for examination in the instant application.
3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicants response and withdrawn.
4. Applicant's arguments filed on 13 April 2009, have been fully considered. New grounds of objection and rejection are as follows.

### ***Response to Amendment***

*Claim rejections maintained*

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The rejection of claims 15-16, 18, 22, 24 and 26, under 35 U.S.C. 103(a) as being unpatentable over Hertel et al. (Eur J Pharmacol 422: 77-81, 2001), in view of Feifel et al. (Brain Res 760: 80-84, 1997), is applied to the amended claims for reasons of record in the Office Action dated 12 November 2008.
6. Applicant argues that Hertel et al. and Feifel et al. fail to teach or suggest improving symptoms of bipolar or depression or anxiety disorder by increasing sensorimotor gating in a subject, or inhibiting serotonin-2A (5HT2A) and/or alpha-1 receptor mediated neural function. Applicant alleges that Hertel et al and Feifel et al. teach that NT69L and PD149163 block the amphetamine induced stimulation of dopamine receptors in contrast to the teachings of the disclosure demonstrating blocking of DOI induced stimulation of 5-HT2A receptors. Applicant further alleges that the references teach that the NT agonist only improves "positive symptoms" of schizophrenia, not the entire "symptom spectrum" of the claimed psychiatric disorders. The references also do not teach that the agonist is a "putative antipsychotic" that modulates the serotonergic and dopaminergic pathways without interacting with the respective receptors. Because of the above reasons, Applicants allege that Hertel et al and Feifel et al. do not "teach or suggest each and every element of Applicant's claimed invention" and therefore, requests withdrawal of the rejection.
7. The "Summary of the Disclosure", and Applicant's arguments in response to the Office Action are acknowledged and fully considered. Applicant is constantly referring to the disclosure and the teachings therein, thus reading

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limitations not recited into the claims. Applicant's arguments have not been found to be persuasive, because arguments that rely on particular distinguishing features are not persuasive when those features are not recited in the claims. In the present situation, there is no requirement for any particular result. Claims 15-18 and 22 only require increasing sensorimotor gating by administration of an effective amount of NT69L to a subject having any anxiety disease, or any depression disease or bipolar disease (please note that 'an' is broadly interpreted by the Office as 'any'), wherein the said symptoms are improved. The claims do not require the mechanism of action of NT69L, be it dopamine and/or serotonergic. The claims also do not require a positive or a negative symptom of a psychiatric disorder. It is noted that USPTO personnel are to give claims their broadest reasonable interpretation in light of the supporting disclosure. *In re Morris*, 127 F.3d 1048, 1054-55, 44 USPQ2d 1023, 1027-28 (Fed. Cir. 1997). Narrow limitation contained in the specification cannot be inferred in the claims where the elements not set forth in the claims are linchpin of patentability. See *In re Philips Industries, Inc. v. State Stove & Mfg. Co.*, 522 F.2d 1137, 186 USPQ 458 (CA6 1975), 237 PTJA A-12. While the claims are to be interpreted in light of the specification, it does not follow that limitations from the specification may be read into claims. On the contrary, claims must be interpreted as broadly as their terms reasonably allow. See *Ex parte Oetiker*, 23 USPQ2d 1641 (BPAI, 1992). Applicant is reminded that the claims define the subject matter of his invention and that the specification cannot be relied upon to read limitations into

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the claims. The fact that Applicant achieved the blocking of stimulation of 5-HT<sub>2A</sub> receptors by using NT69L and PD149163, "since it blocks PPI disruption by DOI which reduces PPI by activation of 5-HT<sub>2A</sub>, but not dopamine receptors", therefore, does not render the claimed invention non-obvious.

8. Additionally, as stated in the previous Office Action (page 4, para 10), Feifel et al. teach that NT analogues can be used as a potential antipsychotic agent for treating the pathology associated with diseases like schizophrenia. As evident from the relevant literature, schizophrenia is an anxiety/depression disorder (Bennett, Aus and NZ J Psychiat 42: 995-1002, 2008; page 996, col 1, para 1). Similarly hyperactivity is shown to be associated with anxiety/depression and sleep disorder (Svestka, Neuroendocrin Lett 29: 65-92, 2008; abstract). Applicant's allegation that the reference teachings would only motivate "the use of NT69L to treat certain symptoms of schizophrenia, namely positive symptoms since only these symptoms are known to be improved by inhibition of dopamine receptors alone", is irrelevant, particularly after considering the claim requirements. Based upon the antipsychotic properties of NT agonist, and based upon the demonstration of improving sensorimotor gating and any symptom of a disease (anxiety/depression/bipolar) as broadly claimed, the administration of INT69L would implicitly result in the blocking of serotonergic and/or dopaminergic receptors to mediate its action, absent any evidence to the contrary. The prior art teaches the administration of NT69L in a subject to treat

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an anxiety disorder for example, and therefore, renders the claimed invention obvious.

9. Furthermore, although claims 24-26 recite a method of inhibiting serotonin-2A receptor mediated neural function, the method steps are the same, i.e. administering NT69L or a NT agonist to achieve the same result in a subject. Because NT agonists inherently have this property, the claimed invention would be prima facie obvious over the combined teachings of the prior art. It is reminded that the discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In view of the above discussion, Applicant's assertion that the "ability to block transmission at serotonin 2A and alpha-1 receptors were not known to be a pharmacological properties of neurotensin agonists prior to the studies described in the present application" is moot, and does not render the invention non-obvious and patentable.

10. The rejection of claims 15-17 and 25 under 35 U.S.C. 103(a) as being

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unpatentable over Hertel et al. (Eur J Pharmacol 422: 77-81, 2001), and Feifel et al. (Brain Res 760: 80-84, 1997), in view of Costa et al. (Eur J Pharm 428: 97-103, 2001), is being applied to the amended claims for reasons of record in the Office Action dated 12 November 2008.

11. Applicant alleges that because the disclosure teaches NT agonists as useful towards a "broader spectrum of diseases and symptoms disorder that could not otherwise be treated with therapeutics that modulated dopaminergic receptor activation alone (as allegedly taught by the cited references)", and because the root of a prima facie obviousness rejection constitutes "the fact that the elements set forth in the claims must be taught by the reference or references when combined", the references as a whole fail to teach or suggest the claimed invention.
12. Applicant's arguments are fully considered, however, are not found to be persuasive for reasons explained above. Since the references in combination teach the elements of the method steps as claimed, using the administration of a NT agonist along with SR48692 in a subject having an anxiety disorder (or hyperactivity for example), thereby increasing sensorimotor gating in such disorders, and because the inhibition of dopaminergic and serotonergic receptor is an inherent property of neurotensin and its agonists, the references implicitly teach or suggest each and every limitation of the claim. Therefore, the claimed invention stands prima facie obvious over the teachings of the combined references.



***Conclusion***

13. No claims are allowed.
14. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).
15. A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is (571) 272-9037. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.
17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD  
24 June 2009

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649